

REMARKS

Status of the claims

Claims 11-21 and 26 are pending in the application. Claims 1-10 and 22-25 are cancelled. Claims 11 and 17 are amended herein. Support for the amendments to claim 11 may be found at least on page 14, lines 9-15 of the specification, as well as the Examples. No new matter has been added with the amendments. As such, entry and consideration thereof are respectfully requested.

Rejections under 35 U.S.C. §103

The Examiner maintains the rejection of claims 11-21 and 26 as being obvious over Van Hees et al. 2002 and VanHees et al. 1999, in view of Junco et al. In response to Applicant's arguments of June 22, 2009, the Examiner points to the ordinary meaning of "recovering" as encompassing "both obtaining, as by separation or isolation, of a product and getting back or identifying a product without necessarily separating or isolating the product." The Examiner cites to the Merriam-Webster OnLine Dictionary in support of his position. The Examiner then states, "While the term is interpreted within the context of the chemical arts, the definition within the chemical arts is not limited to separation or isolation as defined within the chemical arts, therefore the ordinary definition is encompassed by the term." Applicants respectfully note that the Examiner appears to have both stated that the term "is interpreted within the context of the chemical arts" but then not so interpreted the term. Clarification is requested.

The Examiner further states that there are no limitations in the claims that require a depressurization between steps (b) and (d) and that step (d) is not carried out under pressure.

Applicants traverse this rejection and withdrawal thereof is respectfully requested. Claim 11 has been amended, in part, to recite that in step (c) there is a depressurization before the recovering of the active substance/host molecular complex and that step (d) is carried out under atmospheric pressure. Support for these amendments can be found in the Examples.

As noted previously, with the present invention, there is a depressurization between steps (b) and (d) in order to recover the active substance/host molecule complex. Step (d) is, therefore, not carried out under pressure and the mixing of the active substance/host molecule

molecular complex with the agent for interaction with the complex is not carried out in the presence of a pressurized fluid. The dense pressurized fluid is only present in step (b). These features have now been explicitly recited in the claims.

The present invention has two separate reaction steps: a first reaction step, which is carried out under pressure by contacting a dense pressurized fluid with the mixture of the active substance and host molecule; and a second step, which is not carried out under pressure and which is performed in the absence of a dense pressurized fluid. In the second step, the agent for interaction with the active substance/host molecule molecular complex is simply added to the active substance/host molecule molecular complex. See, for example, Example 1 of the specification, which discloses that the mixture of the powder and ammoniacal solution after the "maturing stage" is placed in a ventilated oven at 60°C overnight and, thus, is not carried out in the presence of CO₂ under pressure. The claimed process is therefore clearly distinguished from and unobvious over the one-step process of Van Hees et al. 1999 and 2002. As further previously discussed, the instantly claimed process possesses unexpected improved properties over the disclosures of Van Hees et al. 1999 and 2002.

The secondary reference of Junco et al. fails to compensate for the deficiencies of the Van Hees et al. references. As such the instant invention is neither disclosed nor suggested by Van Hees et al. 1999 and 2002 combined with Junco et al., and withdrawal of the rejection is respectfully requested.

Obviousness-type double patenting

The Examiner further maintains the rejection of claims 11-22 and 26 for obviousness-type double patenting over claims 1-10 and 13 of copending application No. 10/554,058, in view of Van Hees et al. 2002.

Similarly, the rejection of claims 11-21 and 26 for obviousness-type double patenting over claims 1-8 of US Patent No. 7,390,411, in view of Van Hees 2002, has been maintained.

Applicant traverses these rejections and withdrawal thereof is respectfully requested. As discussed above, the present invention is drawn to a process that requires two separate reaction

steps, the first of which is performed under pressure and the second of which is not (see amended claim 11), whereas the method of Van Hees et al. is performed as a single reaction under pressure. The two-reaction/two step method of the invention possesses unexpected advantages over the single-step reaction of Van Hees et al. In addition, it would not have been obvious to modify the method of Van Hees et al. to perform two separate reactions, which would require more time and effort. As such, the present invention of claims 11-21 and 26 is not obvious over the method of claims 1-10 and 12 of co-pending application No. 10/554,058 or claims 1-8 of US Patent No. 7,390,411, in view of Van Hees 2002. As such, withdrawal of the non-statutory obviousness-type double patenting rejections is therefore respectfully requested.

Rejections under 35 U.S.C. §112, 1st paragraph

Claims 11-21 and 26 have been rejected under 35 U.S.C. §112, 1st paragraph, for an asserted lack of enablement. The Examiner asserts that the specification is only enabled for a process wherein the active agent/host molecule molecular complex and agent for interaction are mixed in solution.

Claim 11 has been amended to recite that step (d) is carried out in a semisolid medium. Support for this amendment is found in the specification at least at page 14, lines 9-15. Thus, claim 11 has been amended as described in the specification, i.e. that when the mixing is carried out the agent of interaction is liquid and will simply moisten the complex or form a past with the complex. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §112, 2nd paragraph

Claims 11-21 and 26 have been rejected under 35 U.S.C. §112, 2nd paragraph, as being indefinite. More specifically, the Examiner asserts that the recitation of “soluble inclusion compound” is indefinite because the claim does not define what the inclusion compound is soluble in. Claim 11 has been amended to define the solubility as being “aqueous”. As such, withdrawal of the rejection is respectfully requested.

Claim 17 has been rejected for recitation of "anilide derivatives" and "epipodophyllotoxin derivatives" with the assertion that the steric fit between the host and guest molecule and the solubility are essential features to the technology and it is not clear how the "derivatives" would affect these features. Claim 17 has been amended to delete "derivatives". As such, withdrawal of the rejection is respectfully requested.

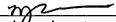
In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, PhD, Reg. No. 40,069, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: **DEC 30 2009**

Respectfully submitted,

By 
MaryAnne Armstrong, PhD
Registration No.: 40,069
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant